

Remarks:

Claims 55-58, 62-65, 120-123, and 139-151 are currently pending. Claim 44 has been canceled and replaced with claim 151, and claims 55, 62, 120, 147, 148, 149, 150, and 151 are independent. Claims 120, 139, 140, 142, 144, and 147-50 have been amended. Claims 45-47 have also been cancelled.

The specification has also been amended to correct a typographical error in the sequence listing. Specifically, page 7 of the sequence listing and the computer readable format that accompanied the application as filed, incorrectly noted that SEQ ID NO. 14 was of simian origin. SEQ ID NO. 14 should have reflected that it was of porcine origin rather than simian. The correction of this error is supported in the specification as filed wherein it is noted at page 12, lines 18-19 wherein it is clearly stated that SEQ ID NO. 14 is porcine CD 151. To correct this error, applicants have amended the specification above and submitted a new sequence listing in computer readable format. This amendment does not incorporate any new matter in that the sequence of SEQ ID NO. 14 did not change at all. Accordingly, Applicant respectfully requests entry of this amendment and the accompanying sequence listing in computer readable format.

Claims 44-47, 139-40, 147 and 150 were rejected under 35 U.S.C. 112, first paragraph, for failing to comply with the written description requirement. Specifically, it was alleged that "there is no description of what is the DNA sequence coding for CD 151 protein or a protein, which has the same functions as CD 151." (office action of 9/30/2005, ¶ 3). Claims 55-58, 62-68, 120-23, 139-46 and 148-49 were also rejected under 35 U.S.C. 112, first paragraph, for containing subject matter insufficiently described in the specification to convey to a person of ordinary skill in the relevant art that the inventors had possession of the claimed invention at the time the application was filed. Specifically, it was alleged that the written description does not support the claimed sequence

variations of SEQ ID No. 14, due in part to the high variance of the claimed genus. Further, that there is no teaching of how the functions of CD 151 are correlated with the DNA sequence coding the protein. Claims 44-47, 120-23, 139-40 and 145-50 were rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to clarify what the function is as used in the phrase “same function as CD 151.” Claims 44-47 were rejected as being anticipated by Testa et al., (US 6,245,898).

Applicants have amended the claims to refer to “porcine” CD 151 and proteins that have the same function as porcine CD 151 as well as that the transformation of the cell line renders the cell line susceptible to infection by PRRSV. Support for these amendments can be found throughout the application, for example at page 5, lines 25-30, page 10, lines 30-31, and at page 12, lines 14-31, and especially in the examples. Applicants submit that the present written description contains sufficient information to convey to persons of ordinary skill in the relevant art that the inventors had possession of the claimed invention at the time the application was filed. Applicants direct the Examiner’s attention to the paragraph on page 12 of the application beginning at line 14 wherein the specific discussion of porcine CD 151 begins. The present invention represents a number of unexpected and important breakthroughs in PRRSV research. Specifically, the present invention provides the first report of the complete porcine mRNA and genomic sequences, and accordingly, the first report of the complete porcine CD 151 sequence. The claimed sequence for porcine CD 151 is listed in the application as SEQ ID No. 14. As explained in the specification, it was determined that porcine CD 151 shares only 84% homology with other known CD 151 sequences, and there are currently no known CD 151 sequences that share more than 84% homology with porcine CD 151. Further, porcine CD 151 introns share little or no homology with any other known CD 151 sequences. (Specification at page 14, line 19). It was also discovered that porcine CD 151 has the ability to bind

the 3' UTR RNA of PRRSV as illustrated by Example 21 and Fig. 11. As mentioned in the specification, this is the first report of a tetraspan molecule having RNA-binding activity. (Specification at page 12, line 8). It was further found that porcine CD 151 has the ability to render previously unaffected cells permissive to infection by PRRSV. The information provided by the present invention was, heretofore, unknown, and as mentioned, unexpected.

The functions of porcine CD 151, with which the present invention is concerned is the PRRSV 3' UTR RNA-binding activity and the ability to render previously unaffected cells permissive to infection by PRRSV. The fact that it is porcine CD 151's genetic sequence which imparts this particular function is implicit from common knowledge in the art. This is a specific function, aimed at limiting the present invention to porcine CD 151 and proteins the perform the same function as CD 151. Contrary to the Examiner's allegations, the specification clearly teaches that the ability of porcine CD 151 to render cells permissive to infection by PRRSV is directly correlated with the DNA sequence coding for the protein, as evidenced by Examples 9, 17, 26 and the discussion. Accordingly, the relevance of the functional limitations added during the previous office action response is clearly supported by the specification. Further, the 3' UTR RNA-binding activity alone necessarily suggests a correlation between the function of porcine CD 151 in the transfected cells and the genetic sequence coding for the protein. Applicants further note that claims 147 and 150 already contain the limitations regarding RNA-binding activity and PRRSV infection susceptibility. Accordingly, any DNA sequence or transformed cell line would necessarily have to have these functions in order to be covered by the current claims.

Applicants maintain that in light of the appreciable genetic differences between porcine CD 151 and other known CD 151 sequences (see specification at page 12, lines 19-22), and the unexpected function of porcine CD 151 in PRRSV infection, proteins which possess the same

function as porcine CD 151 fall well within the scope of the subject matter taught by the present invention. Further, it would be clear to those of ordinary skill in the art that proteins having the “same function as porcine CD 151” will necessarily also share a certain degree of similarity to porcine CD 151 because as previously stated, the function in question is imparted by the genetic or amino acid sequence. In this respect, it is decided case law and Patent Office policy that if a protein sequence is provided in the application, all possible permutations of the nucleic acid sequence coding for the protein sequence are also provided. In this application, even more disclosure is given in that the complete protein is provided, as is the complete DNA sequence giving rise to that protein.

Point mutations and conservative amino acid substitutions are naturally occurring or engineered variations in the genetic code which generally do not affect the overall functionality of the resulting protein for which they code. The entire porcine CD 151 sequence is given by SEQ ID No. 14; a separate sequence need not be provided for every possible genetic variation that would result in the same function, because it is well within the routine skill in the art to modify SEQ ID No. 14, without undue experimentation, to produce a protein that is not 100% identical to porcine CD 151, but which maintains all of its functional limitations. (See e.g., Example 17, at page 35, beginning at line 4, and Example 26 at page 45, beginning at line 10). Example 26 specifically illustrates the RNA-binding activity of porcine CD 151 and infection by PRRSV in the presence of certain genetic mutations (i.e., without 100% sequence identity). Accordingly, the functional limitations of the present invention are not merely gratuitous inclusions, but serve the distinct function of distinguishing porcine CD 151 and proteins with the same functions as porcine CD 151, from other sequences and proteins that lack this RNA-binding activity or cannot render previously unaffected cells permissible to infection by PRRSV.

Moreover, the recited limitations in degrees of homology found in claims 55-58, 62-65, and 120-23 would be commonly understood by persons of ordinary skill in the relevant art to represent DNA sequences that are neither taught nor suggested by the prior art, but which fall properly within the scope of the present invention given that the entire porcine CD 151 genomic sequence and thus, its homology to other CD 151 sequences, was heretofore unknown. By claiming various homologies and proteins with the same function as porcine CD 151, Applicants are merely accounting for the infinite number of small variations that could occur in a genetic sequence, but which would not result in a substantially different functioning protein. Further, such variations could be purposefully engineered to avoid direct infringement of a claim limited to SEQ ID No. 14 while reaping the benefits of the novel and inventive functions of porcine CD 151. Accordingly, requiring Applicants to select a single sequence would unduly and prejudicially limit the scope of the present invention.

By limiting the claims in terms of function and homology, Applicants have fairly restricted the scope of the present invention in the most realistic way possible, to achieve the appropriate amount of protection for the present invention, while at the same time providing adequate notice to persons of ordinary skill in the relevant art of the scope and breadth of what is being claimed and avoiding the teachings and suggestions of the prior art.


The present amendments also overcome the prior art of record. Testa et al., discloses human CD 151 (SEQ ID No. 2), and Fitter et al., discloses the mouse homologue of CD 151, whereas the present invention is directed towards porcine CD 151. The present application is limited to porcine CD 151. As previously discussed, porcine CD 151 shares less than 84% homology with other known sequences of the prior art. Further, the alignment of CD 151 amino acid sequences, enclosed herewith, demonstrates the distinctiveness of the porcine CD 151 from those of prior art.

Specifically, simian CD 151 has only 83% identity with porcine CD 151, whereas human, murine, and bovine CD 151 found in the prior art have 95%, 92%, and 89% identities, respectively, with simian CD 151, but only 84-86% identity with porcine CD 151. Accordingly, the present invention is neither anticipated, nor rendered obvious by the prior art of record.

In light of the foregoing, the present application should now be in condition for allowance and a Notice of Allowance is courteously solicited.

Any additional fee due in connection with this amendment should be applied against Deposit Account 19-0522.

Respectfully submitted,

By   
Tracey S. Truitt, Reg. No. 43,205  
HOVEY WILLIAMS LLP  
2405 Grand Boulevard, Suite 400  
Kansas City, Missouri 64108  
816/474-9050